

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC. PELVIC REPAIR
SYSTEMS PRODUCTS LIABILITY
LITIGATION

Master File No. 2:12-MD-02327
MDL 2327

ETHICON WAVE 3 CASES LISTED IN
EXHIBIT A

JOSEPH R. GOODWIN U.S. DISTRICT
JUDGE

**MEMORANDUM IN SUPPORT OF DEFENDANTS' SUPPLEMENTAL MOTION TO
EXCLUDE AND NOTICE OF ADOPTION OF PRIOR DAUBERT MOTION AND
REPLY BRIEF OF JOHN MIKLOS, M.D. FOR WAVE 3**

Defendants Ethicon, Inc., Ethicon, LLC and Johnson & Johnson (collectively, "Ethicon"), submit this supplemental memorandum in further support of their motion to exclude certain opinions of Dr. John Miklos for Ethicon Wave 1 cases, Dkt. Nos. 2032 (motion), 2034 (memorandum in support) and supporting Reply brief, Dkt. 2227, which have been adopted with respect to the Wave 3 cases set forth in Exhibit A of Ethicon's notice of adoption, filed contemporaneously herewith.

INTRODUCTION

In its Wave 1 Motion to Exclude Dr. Miklos, Ethicon moved to exclude Dr. Miklos's opinions and testimony on the following bases, which are renewed for Wave 3: (1) Dr. Miklos was not qualified to opine on biocompatibility characteristics of the mesh used in TVT Secur; (2) Dr. Miklos's opinions on design defect lacked a reliable basis; (3) Dr. Miklos's opinions on safer alternative products were unreliable; (4) Dr. Miklos was not qualified to testify regarding the adequacy of the TVT Secur Instructions for Use (IFU); (5) Dr. Miklos's opinions regarding inadequate training were irrelevant; and (6) Dr. Miklos should not be permitted to testify as to Defendants's knowledge, state of mind, and alleged bad acts. (Dkt. 2034). This Court held that

(1) Dr. Miklos would not offer opinions that laser-cut mesh changes the properties of mesh, and the motion to exclude those opinions was therefore moot; (2) Dr. Miklos's opinions on failure rates of TVT Secur would be better suited for cross examination than as grounds for exclusion; (3) Dr. Miklos's testimony on safer alternatives was reliable and admissible; and (4) Dr. Miklos was not qualified to offer opinions on what an IFU should or should not include; as well as entering its order on recurring issues excluding, among other things, any state-of-mind and legal-conclusion expert testimony, as well as any testimony that is solely a conduit for corporate information and documents. (Dkt. 2669).

In addition to the arguments for exclusion raised in Wave 1, this Court also should preclude Dr. Miklos from offering opinions regarding alleged design defects in Ethicon's TVT Secur product. Supplementing the arguments set forth in Ethicon's briefings filed against Dr. Margolis for Ethicon Wave 1 cases, Ethicon submits that Dr. Miklos's opinions related to design defect are unsupported and unreliable. Moreover, Dr. Miklos is not qualified to offer them.

LEGAL ARGUMENT

I. Dr. Miklos's Opinions on the Allegedly Defective Design of the TVT Secur Are Unreliable.

In his report, Dr. Miklos contends that several elements of the TVT Secur are "design flaws" that cause injury to patients: the mechanism for insertion; difficulty in properly tensioning the mesh, release difficulties, and difficulty in removing the insertion device after fixation; the "fixation tips" not staying in place; lower success rates, bladder perforations, and excessive bleeding. Ex. B, Rule 26 Expert Report of John Miklos M.D. ("Miklos Rep.") at 13-14. Some of these alleged "design flaws" are not actually *elements of the TVT Secur design*—for example, lower success rates, bladder perforations, and excessive bleeding are outcomes or injuries, not

elements of design. These alleged design defects should be excluded at the outset because they are not *design features* of the product at issue.

The remainder of the alleged design flaws of which Dr. Miklos complains are not supported by reliable scientific evidence. Dr. Miklos's expert report is, rather, replete with citations to Ethicon's internal documents. *See, e.g.*, Miklos Rep. at 13 & n.23 (citing an internal email and Ethicon presentation for the proposition that "[t]he TVT-S insertion method and design often caused the anchoring to dislodge, difficulty in properly tensioning the mesh, difficulty in removal of the insertion device after fixation, and lower success rate than other available SUI products"); 14 (citing an "August 19, 2007 internal PowerPoint presentation" for the proposition that the following design flaws exist with respect to TVT Secur: "(1) insertion difficulties; (2) releasing difficulties; (3) fixation tips not staying in place; (4) bladder perforations; (5) excessive bleeding; [and] (6) failures – tensioning"). Dr. Miklos is merely parroting corporate documents in support of his opinions, which this Court has already held, in its ruling on Ethicon's Wave 1 motion, that Dr. Miklos may not do. *See* Dkt. 2669, at 11 (excluding Dr. Miklos from offering testimony "that is solely a conduit for corporate information"); *see also Hershberger v. Ethicon Endo-Surgery, Inc.*, 2012 WL 52444287, at *7-8 (S.D. W. Va. Feb. 15, 2012) (Johnston, J.) (excluding an expert from testifying as to product defect, where expert's opinion was not based on his experience or education, but rather was based on other experts' testimony and the defendant's corporate documents); *Hines v. Wyeth*, 2011 WL 2680842, at *5 (S.D. W. Va. 2011) (Copenhaver, J.) (excluding expert testimony in part because it "merely regurgitates factual information that is better presented directly to the jury rather than through the testimony of an expert witness").

Dr. Margolis does not cite any reliable scientific literature in the section of his report discussing design flaws of TVT Secur. (*See* Miklos Rep. at 13 & nn.20-25) His regurgitation of internal company documents requires no expertise at all. *See also Sullivan v. Alcatel-Lucent USA Inc.*, No. 12 C 07528, 2014 WL 3558690, at *5 (N.D. Ill. July 17, 2014) (excluding expert testimony based on internal company documents, observing that the expert “simply reads and interprets documents” but “does not draw on any expert qualifications or experience. As such, his readings and interpretations are merely gratuitous, and would be unhelpful to a prospective jury”). Dr. Miklos’s review of company emails, memos and anecdotal experiences falls far short of sound scientific method. His “method” certainly does not rise to “same level of intellectual rigor that characterizes the practice of an expert in the relevant field.” *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999).

Moreover, Dr. Miklos failed to shore up the reliability of his opinions during his deposition in Wave 1—in fact, he acknowledged that surgeon skill plays an important role in patient outcomes, a role that he apparently did not account for in claiming that specific design flaws in TVT Secur necessarily cause certain injuries. For example, Dr. Miklos identified the following design flaws in his deposition: (1) the “razor blade” insertion tip, which he deemed “unprecedented”; (2) the “horrendous” releasing mechanism as documented in “the internal documents”; (3) a “polysorb” material, an “absorbable material that has never been utilized before in the pelvic floor”; (4) and the facts that surgeons “can’t control the trajectory of” the needle driver used for insertion and “have difficulty adjusting the tension” of the device “because [they’re] just pushing.” Ex. C, Miklos 4/8/16 Dep. Tr. 54:4-55:23.

Not only did he fail to support his personal opinions as to the “horrendous” flaws of the TVT Secur with actual scientific literature, his opinions demonstrate that he failed to account for

the impact of a surgeon's skill and technique on the outcomes of the surgeries. Indeed, Dr. Miklos acknowledged that the surgeon's skill set and technique are the most important factors in the use of a device, and not the device itself. Miklos 4/8/16 Dep. Tr. 11:7-12; Ex. D, Miklos 2/6/15 Dep. Tr. 147:12-148:3. He acknowledged that TVT Secur works in various surgeons' hands. Miklos 4/8/16 Dep. Tr. 55:24-56:4 ("Q. So it's your opinion that it's defective because of those attributes, but we can agree that even with those attributes . . . which you find objectionable or defective, surgeons still can get good results with TVT-Secur as evidenced by peer reviewed public literature that you are aware of, correct? A. Absolutely. . ."). In criticizing the TVT Secur because surgeons "can't control the trajectory" of the needle driver or "have difficulty adjusting the tension," he fails to account for or provide a basis for rejecting the fact that differently skilled surgeons may not in fact have those problems—and the possibility that the problems may be due to a difference in skill set, not defects in the TVT Secur's design. Dr. Miklos's opinions regarding the purported design defect are conclusory, speculative, and unsupported by scientific literature or a sound methodology. They should be excluded.

II. Dr. Miklos is Not Qualified to Opine on Design Defect.

Ethicon contended in its Wave 1 Motion that Dr. Miklos was not qualified to opine on the design defect issues he identifies with respect to the TVT Secure. Dkt. 2034 at 3. All of the design defect issues that Dr. Miklos identifies have to do with the way in which the TVT Secur interacts with living tissue—*e.g.*, whether it properly inserts and releases, the way in which the "polysorb" material is absorbed into the body, whether its design causes bladder perforations and bleeding, and so forth. *See* Miklos Rep. at 13, 14; Miklos 4/8/16 Dep. Tr. 54:4-55:23. This argument was not addressed in the Court's ruling on Ethicon's Wave 1 Motion, and Ethicon adopts and reasserts its arguments herein. *See* Dkt. 2669 at 6. In Wave 3, the Court should

exclude Dr. Miklos's testimony on design defect for the additional reason that he is not qualified to opine on the identified defects that implicate biocompatibility expertise. Dr. Miklos is admittedly not an expert in biocompatibility issues. He has had no training or education on biomaterial medical device design. Miklos 2/6/15 Dep. Tr. 246:23-25. He has never been involved in any bench research on polypropylene mesh, and he has no training or education in polymer chemistry. Miklos 2/6/15 Dep. Tr. 247:3-8. His lack of expertise in this area necessarily affects the permissible scope of his testimony.

CONCLUSION

Ethicon respectfully requests the Court grant their Motion to Exclude the Testimony of John Miklos M.D.

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I, Christy D. Jones, certify that on this day I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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